

REMARKS

In response to the Non-Final Office Action mailed April 27, 2007, reconsideration of the application is requested in view of the pending claims and following remarks.

I. THE PENDING CLAIMS

Claims 15-19, 21, 33-37, 39-49, and 51-60 are pending. Claims 1-14, 20, 22-32, 38, 50, and 61 are canceled. No new matter has been introduced in the amendments.

Applicants have amended independent claims 15 and 33 by deleting “or staging anthrax infection” and inserting “the presence of bacterial poly glutamic acid (PGA)”, replacing “ γ _D-PGA” with “PGA,” and deleting “anthrax infection, or stage thereof” and inserting “bacterial infection by PGA-producing pathogens.” Claim 33 has further been amended by deleting “a level of.” Independent claims 40 and 51 have been amended by replacing the first recitation of “anthrax” with “by a PGA-producing bacterium,” the second recitation of “anthrax” with “said,” and “ γ _D-PGA” with “PGA.”

Dependent claim 21 has been amended by deleting “ γ _D-PGA” and inserting “PGA” and by replacing “*Bacillus anthracis*” with “said PGA-producing pathogen.” Dependent claims 34, 39, 45, and 56 have been amended by replacing “ γ _D-PGA” with “PGA.”

Applicants submit that the rejections based on lack of written description under 35 U.S.C. § 112, second paragraph, are overcome in view of the amendments and arguments presented in the response below. Accordingly, entry of these amendments is requested.

II. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

On page 3, section 8 of the Office Action, the Examiner considers claims 15-19, 21, 33-37, 39-49 and 51-60 as being indefinite under 35 U.S.C. §112, second paragraph. More specifically, the Examiner contends that there are two reasons for issuing an indefinite rejection. First of all, it is “unclear” for one skilled in the art to distinguish between a *Bacillus licheniformis* infection and *Bacillus anthracis* infection if the claimed methods “do not recite precipitin patterns” and instead recites by means of “merely detecting γ _D-PGA or level of γ _D-PGA.” Secondly, the specificity of the antibody is not part of the claimed methods and, therefore, it is “unclear” for one skilled in the art to determine “the level of γ _D-PGA utilizing antibodies without a specificity for γ _D-PGA.”

Applicants respectfully traverse this rejection.

With regard to the Examiner's contention that "it is unclear how one distinguishes infection with *Bacillus licheniformis* and infection with *Bacillus anthracis*," there is no need to make such a distinction. Independent claims 15, 33, and 40 are directed to detecting the presence of soluble PGA resulting from infection by PGA-producing pathogens. As explained on page 5, ¶19, of the specification, "the method allows for a *diagnostic* test that is faster than current culture conditions, easier than nucleic acid hybridization techniques, and is not dependent on the presence of viable pathogen that would not be present in the event that a patient had been treated with antibiotics. Moreover, an assay for blood or serum PGA can rapidly assess the microbial load in a patient and aid in an assessment of patient prognosis" (emphasis added). Similarly, independent claim 51 is directed to "[a] method for evaluating progression of infection by a PGA-producing bacterium." Thus, distinction between infection with *Bacillus licheniformis* and infection with *Bacillus anthracis* need not be made.

With respect to the Examiner's assertion regarding the specificity of the antibody, the invention provides antibodies specific for γ_D -PGA, γ_L -PGA, or other capsular polypeptides that can be used for the diagnosis, prevention, or treatment of infection by PGA-producing pathogens. As pointed out on page 16, ¶71, of the specification, "[t]he antibodies can be polyclonal, monoclonal, chimeric, humanized, scFV, FV, Fab', Fab, F(ab')₂, or other types of antigen-binding molecules or fragments." The use of monoclonal antibodies is but one example set forth by the Applicants in the specification. Additionally, Applicants have amended all pending claims to recite "PGA." Accordingly, the amendments render the rejection moot.

Based on the foregoing remarks and claim amendments, Applicants submit that claims 15-19, 21, 33-37, 39-49 and 51-60 are no longer indefinite. Rejection under section 112, ¶2 should be withdrawn.

CONCLUSION

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. The Commissioner is hereby authorized to charge any payment deficiency to Deposit Account No. 19-2380 referring to Attorney Docket No. 031673-003000.

Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicants' representative designated below.

Respectfully submitted,

Date: October 25, 2007

/Jeffrey A. Lindeman, Reg. # 34,658/
Jeffrey A. Lindeman
Reg. No. 34,658

Customer No. 022204
NIXON PEABODY LLP
Suite 900
401 9th Street, N.W.
Washington, DC 20004-2128
Tel.: (202) 585-8000
Fax: (202) 585-8080